



PTO/SB/08A (10-01)

Approved for use through 10/31/2002. OMB 0651-0031

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² Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 5

Substitute for form 1449A/PTO		<i>Complete if Known</i>	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Application Number	10/790,562
		Filing Date	March 1, 2004
		First Named Inventor	Hateboer et al.
		Group Art Unit	1683 1636 <i>west</i>
		Examiner Name	W. Schlapkohl
Sheet	1	of	5
		Attorney Docket Number	2578-4038.3US

U.S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

Examiner Signature	<u>Jeffrey Kroll</u>	Date Considered	3-15-2006
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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				First Named Inventor	Hateboer et al.
				Group Art Unit	1653 1636 <i>way</i>
				Examiner Name	W. Schlapkohl
Sheet	2	of	5	Attorney Docket Number	2578-4038.3US

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			
<i>WLF</i>		ALKHATIB et al., "Expression of Bicistronic Measles Virus P/C mRNA by Using Hybrid Adenovirus: Levels of C Protein Synthesized In Vivo Are Unaffected by the Presence or Absence of the Upstream P Initiator Codon," Journal of Virology, November 1988, pp. 4059-4068, Vol. 62, No. 11.			T ²
<i>WLF</i>		ALKHATIB et al., "High-Level Eukaryotic In Vivo Expression of Biologically Active Measles Virus Hemagglutinin by Using an Adenovirus Type 5 Helper-Free Vector System," Journal of Virology, August 1988, pp. 2718-2727, Vol. 62, No. 8.			
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<i>WLF</i>		BROWN et al., "Evaluation of Cell Line 293 for Virus isolation in Routine Viral Diagnosis," Journal of Clinical Microbiology, April 1986, pp. 704-708, Vol. 23, No. 4.			
<i>WLF</i>		BUKREYEV et al., "Recombinant Respiratory Syncytial Virus from Which the Entire SH Gene Has Been Deleted Grows Efficiently in Cell Culture and Exhibits Site-Specific Attenuation in the Respiratory Tract of the Mouse," Journal of Virology, December 1997, pp. 8973-8982, Vol. 71, No. 12.			
<i>WLF</i>		CARAVOKYRI et al., "Constitutive Episomal Expression of Polypeptide IX (pIX) in a 293-Based Cell Line Complements that Deficiency of pIX Mutant Adenovirus Type 5," Journal of Virology, November 1995, pp. 6627-6633, Vol. 69, No. 11.			
<i>WLF</i>		Certificate of deposit of the PER.C6 cell line (ECACC deposit under number 96022940).			
<i>WLF</i>		CICCARONE et al., "Lipofectamine 2000 Reagent for Transfection of Eukaryotic Cells," Focus, 1999, pp. 54-55, Vol. 21, No. 2.			
<i>WLF</i>		COTE et al., Serum-Free Production of Recombinant Proteins and Adenoviral Vectors by 293SF-3F6 Cells, Biotechnology and Bioengineering, September 5, 1998, pp. 567-75, Vol. 59, No. 5.			
<i>WLF</i>		DUBRIDGE et al., "Analysis of Mutation in Human Cells by Using an Epstein-Barr Virus Shuttle System," Molecular and Cellular Biology, January 1987, pp. 397-387, Vol. 7, No. 1.			
<i>WLF</i>		ENDO et al., Growth of Influenza A Virus in Primary, Differentiated Epithelial Cells Derived from Adenoids, Journal of Virology, Mar. 1996, pp. 2055-58, Vol. 70, No. 3.			
<i>WLF</i>		FALLAUX et al., Characterization of 911: A New Helper Cell Line for the Titration and Propagation of Early Region I-Deleted Adenoviral Vectors, Human Gene Therapy, January 20, 1996, pp. 215-222, Vol. 7.			

Examiner Signature	<i>WLF slapkohl</i>	Date Considered	3-15-2006
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				Group Art Unit	1653 1636 <i>Wolf</i>
				Examiner Name	W. Schlapkohl
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<i>Wolf</i>		Figure 1 submitted by Opponent I.		T ²
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<i>Wolf</i>		GARNIER et al., Scale-up of the adenovirus expression system for the production of recombinant protein in human 293S cells, Cytotechnology, 1994, pp. 145-55, Vol. 15.		
<i>Wolf</i>		GenBank Accession No. X02996.1, 1993, "Adenovirus type 5 left 32% of the genome."		
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<i>Wolf</i>		GRAHAM et al., "Characteristics of a Human Cell Line Transformed by DNA from Human Adenovirus Type 5," J. Gen. Virol., 1997, pp. 59-72, Vol. 36.		
<i>Wolf</i>		GRAHAM et al., "Growth of 293 cells in suspension culture," J Gen Virol, March 1987, pp. 937-940, Vol. 68.		
<i>Wolf</i>		GRAHAM, Cell Lines, Promochem (visited 04.10.2005) <http://www.lgc.promochem-atcc.com/SearchCatalogs/longview.cfm?view=ce,1146678...>.		
<i>Wolf</i>		HOLZER et al., "Construction of a Vaccinia Virus Deficient in the Essential DNA Repair Enzyme Uracil DNA Glycosylase by a Complementing Cell Line," Journal of Virology, July 1997, pp. 4997-5002, Vol. 71, No. 7.		
<i>Wolf</i>		INOUE et al., Production of Recombinant Human Monoclonal Antibody Using ras-Amplified BHK-21 Cells in a Protein-free Medium, Biosci. Biotech. Biochem., 1996, pp. 811-17, Vol. 60, No. 5.		
<i>Wolf</i>		Interlocutory Decision of the Opposition Division of 21 July 2003 in the case EP 0 695 351(European application 94 913 174.2)		

Examiner Signature	<i>Wolfgang Schlapkohl</i>	Date Considered	3-15-2006
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Examiner Name	W. Schlapkohl

Attorney Docket Number 2578-4038.2US

NON PATENT LITERATURE DOCUMENTS

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<i>wolf</i>		LOPEZ et al., Efficient production of biologically active human recombinant proteins in human lymphoblastoid cells from integrative and episomal expression vectors, Gene, 1994, pp. 285-91, Vol. 148.	
<i>wolf</i>		LUTZ et al., "The Product of the Adenovirus Intermediate Gene IX Is a Transcriptional Activator," Journal of Virology, July 1997, pp. 5102-5109, Vol. 71, No. 7.	
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<i>wolf</i>		MERTEN et al., Production of Influenza Virus in Cell Cultures for Vaccine Preparation, Exp Med Biol., 1996, pp. 141-51, Vol. 397.	
<i>wolf</i>		NEUMANN et al., "Generation of influenza A viruses entirely from cloned cDNAs," Proc. Natl. Acad. Sci., August 1999, pp. 9345-9350, Vol. 96.	
<i>wolf</i>		Notice of Opposition to a European Patent for 1 161 548 by Serono.	
<i>wolf</i>		Opposition against European patent 1 108 878 B1 filed October 5, 2005 in the name and on behalf of CEVEC Pharmaceuticals GmbH.	
<i>wolf</i>		Opposition against European patent 1 161 548 B1 filed November 16, 2005, in the name and on behalf of CEVEC Pharmaceutical GmbH.	
<i>wolf</i>		Opposition against European patent 1108787 filed October 5, 2005 in the name and on behalf of Probiogen AG.	
<i>wolf</i>		ORY et al., "A stable human-derived packaging cell line for production of high titer retrovirus/herpes simplex virus G pseudotypes," Proc. Natl. Acad. Sci., October 1996, pp. 11400-11406, Vol. 93.	

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Examiner Name	W. Schlapkohl

Attorney Docket Number 2578-4038.3US

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<i>wolf</i>		RHIM et al., "Development of Human Cell Lines from Multiple Organs," Annals of the New York Academy of Sciences, 2000, pp. 16-25, Vol. 919.	
<i>wolf</i>		SPECTOR et al., "Regulation of Integrated Adenovirus Sequences During Adenovirus Infection of Transformed Cells," Journal of Virology, December 1980, pp. 860-871, Vol. 36, No. 3.	
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<i>wolf</i>		YEAGER et al., Constructing immortalized human cell lines, Current Opinion Biotechnology, 1999, pp. 465-69, Vol. 10.	
<i>wolf</i>		YEH et al., Adenoviral Vectors, pp. 25-42 of "Concepts in Gene Therapy," Publisher: Walter de Gruyter, New York.	
Examiner Signature	<i>wolf</i>		Date Considered 3-15-2006

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Attorney Docket Number 2578-4038.3US

U.S. PATENT DOCUMENTS

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		Number - Kind Code ³ (if known)			
<i>May</i>		US- 4,703,008	10-27-1987	Lin	
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		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
<i>May</i>		#WO 95/05465	02-23-1995	Amgen Inc.		
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		#WO 98/44141	10-08-1998	The University of British Columbia		
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		#WO 01/38362 A2	05-23-2001	Crucell Holland B.V.		
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		#WO 03/038100 A1	05-08-2003	Crucell Holland B.V.		
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		#WO 2004/003176	01-08-2004	The Kenneth S. Warren Institute, Inc.		
		#WO 2004/099396	11-18-2004	Crucell Holland B.V.		
<i>May</i>		#EP 0 411 678	02-06-1991	Genetics Institute, Inc.		

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OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

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May		#GHOSH-CHOWDHURY et al., Protein IX, a minor component of the human adenovirus capsid, is essential for the packaging of the full length genome, The EMBO Journal, 1987, NOV 1987, Vol. 6.	
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		#NCBI Entrez Nucleotide accession number NC_002018. DUPLICATE	
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Examiner Signature	<i>May Schlapkohl</i>		Date Considered 3-15-2006

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¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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of

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Complete if Known

Application Number	10/790,562
Filing Date	March 1, 2004
First Named Inventor	Hateboer et al.
Group Art Unit	To be assigned 1636 waf
Examiner Name	To be assigned SCHLAPKOHLM waf
Attorney Docket Number	2578-4038 31JS

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
<i>waf</i>		#CARROLL et al., Abstract, Differential Infection of Receptor-modified Host Cells by Receptor-Specific Influenza Viruses, Virus Research, Sep. 1985, pp. 165-79, Vol. 3, No. 2.	
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		#CRONAN, Abstract, Biotinylation of Proteins in-vivo a post-translational modification to label purify and study proteins, Journal of Biological Chemistry, June 25, 1990, pp. 10327-33, Vol. 265, No. 19.	
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		#GRABENHORST et al., Construction of stable BHK-21 cells coexpressing human secretory glycoproteins and human Gal(beta-1-4)GlcNAc-R alpha-2,6-sialyltransferase alpha-2,6-Linked NeuAc is preferentially attached to the Gal(beta-1-4)GlcNAc(beta-1-2)Man(alpha-1-3)-branch of diantennary oligosaccharides from secreted recombinant beta-trace protein, Eur. J. Biochem. 1995, pp. 718-25, Vol. 232, No. 3, Berlin, Germany.	
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		#WEIKERT et al., Engineering Chinese hamster ovary cells to maximize sialic acid content of recombinant glycoproteins, Nature Biotechnology, November 1999, pp. 1116-21, Vol. 17, No. 11, Nature Pub. Co., New York, NY, US.	
<i>waf</i>		#MINCH et al., Tissue Plasminogen Activator Coexpressed in Chinese Hamster Ovary Cells with alpha(2,6)-Sialyltransferase Contains NeuAc-alpha(2,6)Gal-beta(1,4)Glc-N-AcR Linkages, Biotechnol. Prog., 1995, pp. 348-51, Vol. 11, No. 3.	
Examiner Signature	<i>waf schlapkohl</i>	Date Considered	3-15-2006

#Pursuant to 37 C.F.R. § 1.98(d), copies of the previously identified patents are not being provided since they were previously cited by or submitted to the Office in the following prior application:

Serial No.: 09/549,463

Filed: September 3, 2002

For: RECOMBINANT PROTEIN PRODUCTION IN A HUMAN CELL, which application is being relied upon for an earlier filing date under 35 U.S.C. § 120.

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Substitute for form 1449A/PTO		<i>Complete if Known</i>	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Application Number	To be assigned
		Filing Date	March 1, 2004
		First Named Inventor	Hateboer et al.
		Group Art Unit	To be assigned 1636 <i>uat</i>
		Examiner Name	To be assigned SCHLAPKOML <i>uat</i>
(use as many sheets as necessary)			
Sheet	1	of	2
		Attorney Docket Number	2578-4038.3US

U.S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

Examiner Signature	<i>ms/cleekhoff</i>	Date Considered	3-15-2006
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet

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Application Number	To be assigned
Filing Date	March 1, 2004
First Named Inventor	Hateboer et al.
Group Art Unit	To be assigned 1636 <i>maf</i>
Examiner Name	To be assigned SCHLAPKOHL <i>maf</i>
Attorney Docket Number	2578-4038.3US

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

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<i>maf</i>		*PCT International Search Report, PCT/NL00/00247, dated October 9, 2000, 3 pages.	
<i>maf</i>		*GHOSH-CHOWDHURY et al., Protein IX, a minor component of the human adenovirus capsid, is essential for the packaging of the full length genomes, The EMBO Journal, 1987, pp. 1733-39, Vol. 6, No. 6.	
<i>maf</i>		*LOUIS et al., Cloning and Sequencing of the Cellular-Viral Junctions from the Human Adenovirus Type 5 Transformed 293 Cell Line, Virology, 1997, pp. 423-29, Vol. 233.	
<i>maf</i>		*NCBI Entrez Nucleotide accession number U38242.	
<i>maf</i>		*NCBI Entrez Nucleotide accession number NC_002018.	
<i>maf</i>		*NCBI Entrez Nucleotide accession number X02996 J01967 J01968 J01970 J01971 J01972 J01974 J01976 J01977 J01978 J01979 K00515 V00025 V00026 V00027 V00029.	
<i>maf</i>		*SETOGUCHI et al., "Stimulation of Erythropoiesis by in vivo gene therapy: Physiologic consequences of transfer of the human erythropoietin gene to experimental animals using an adenovirus vector," Blood, November 1, 1994, pp. 2946-53, Vol. 84, No. 9.	

Examiner Signature	<i>maf/schlapkohl</i>	Date Considered	3-15-2006
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